DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 12, 2014

Bovie Medical Corporation
Mr. Moshe Citronowicz
Senior Vice-President
5115 Ulmerton Road
Clearwater, Florida 33760

Re: K142975
Trade/Device Name: Bovie Ultimate ™ High Frequency Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 2, 2014
Received: October 14, 2014

Dear Mr. Citronowicz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142975

Device Name

Bovie Ultimate™ High Frequency Electrosurgical Generator

Indications for Use *(Describe)*

The Bovie Ultimate™ High Frequency Electrosurgical Generator is indicated for delivery of RF energy and/or helium gas plasma to cut, coagulate, and ablate soft tissue during open and laparascopic surgical procedures. The J-Plasma portion of the generator can be used only with dedicated Bovie J-Plasma handpieces

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

(Submitted As Required per 21 CFR 807.92)

GENERAL INFORMATION:

Submitter Name:	Bovie Medical Corporation
Establishment Registration Number:	3007593903
Submitter Address:	5115 Ulmerton Road Clearwater, Florida 33760-4004 United States of America
Submitter Telephone Number:	(727) 803-8521
Submitter FAX Number:	(727) 322-4465
Contact Person:	Moshe Citronowicz Senior Vice-President
Date Prepared:	October 2, 2014

DEVICE IDENTIFICATION:

Proprietary Name:	**Bovie Ultimate™ High Frequency Electrosurgical Generator**
Common Name:	Electrosurgical Generator
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Model Number:	BVX-100H
Classification:	21CFR 878.4400; Class II; Product Code GEI
Legally Marketed Predicate Device(s):	510(k) Number: K134054 Primary Predicate Device Name: Bovie IDS-310 High Frequency Electrosurgical Generator Manufacturer: Bovie Medical Corporation 510(k) Number: K090586 Secondary Predicate Name: Bovie ICON GS Generator

Manufacturer: Bovie Medical Corporation

510(k) SUMMARY

(Submitted As Required per 21 CFR 807.92)

Indications

The Bovie Ultimate™ High Frequency Electrosurgical Generator is used for delivery of RF energy and/or helium gas plasma to cut, coagulate, and ablate soft tissue during open and laparascopic surgical procedures. The J-Plasma portion of the generator can be used only with dedicated Bovie J-Plasma handpieces.

Device Description/Characteristics

The Bovie Ultimate™ High Frequency Electrosurgical Generator (BVX-100H) is a multipurpose electrosurgical device used for delivery of RF energy and/or helium gas plasma to cut, coagulate, and ablate soft tissue during open and laparascopic surgical procedures. The J-Plasma portion of the generator can be used only with dedicated Bovie J-Plasma handpieces. The generator combines the features of two cleared electrosurgical generators. The device is intended to be used in the Hospital Operating Room environment.

It features two (2) cut modes up to 300 watts, three (3) blend modes, three (3) coagulation modes, and three (3) bipolar modes. There is a characteristic electrical wave form associated with each mode. The electrical properties of the waveform (frequency and duration) produce the clinical effect (i.e. cut, coagulation). The shape and duration of waveforms are comparable between the generator and predicate devices. The generator offers one (1) monopolar handpiece output, one (1) monopolar foot controlled output, one (1) bipolar handpiece output, one (1) bipolar foot controlled output, and one J Plasma (helium) gas outlet. The generator has a return electrode contact and quality monitoring system (NEM) to reduce the risk of patient burns at the return electrode site. The pad-sensing feature allows the user to use either a split or solid return electrode. This feature is not required when using Helium gas mode for soft tissue coagulation. The Bovie Ultimate™ High Frequency Electrosurgical Generator contains a single software component that is solely used to support the user interface.

The generator is designed to comply with applicable Medical Electrical Equipment safety standards, including electromagnetic compatibility and other safety standards. It is also designed to meet the requirements of the European **Restriction of Hazardous Substances Directive** (2011/65/EU) directive.

The device consists of the generator, power cord, and a User's Guide. The main device components are a front panel containing the power button, wattage selection buttons, gas flow (rate) selection buttons, pulsing, LED numeric displays, alarm and return electrode indicator lights, and connector ports for accessories. The back panel consists of Helium

gas access ports, footswitch ports, volume controls, a power cord outlet, and a fuse. Internal components include printed circuit boards, speakers, and cabling.

Bench testing was performed to demonstrate that the generator met design specifications and to establish substantial equivalence with predicate devices. Device testing and evaluation demonstrated compliance with the following:

IEC 60601-1: 2005
Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance

510(k) SUMMARY

(Submitted As Required per 21 CFR 807.92)

IEC 60601-1-2: 2007
Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

IEC 60601-2-2: 2007
Medical Electrical Equipment - Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Substantial Equivalence:

Characteristic	**Bovie Ultimate™ High Frequency Electrosurgical Generator** **(This Submission)**	**Bovie IDS-310 High Frequency Electrosurgical Generator** **(K134054)** **Primary Predicate**	**Bovie ICON GS Generator** **(K090586)** **Secondary Predicate**
Regulation and Product Code	21 CFR 878.4400 / GEI	21 CFR 878.4400 / GEI	21 CFR 878.4400 / GEI

Intended Use	Is used for delivery of RF energy and/or helium gas plasma to cut, coagulate, and ablate soft tissue during open and laparascopic surgical procedures. The J-Plasma portion of the generator can be used only with dedicated Bovie J-Plasma handpieces.	Is used to deliver RF energy via an assortment of surgical devices to cut and coagulate different kinds of tissue.	Utilizes helium gas for the coagulation of soft tissues during open soft tissue surgery.
Energy Type	High Frequency (RF)	High Frequency (RF)	High Frequency (RF)
Output	Monopolar and Bipolar	Monopolar and Bipolar	Monopolar and Bipolar

510(k) SUMMARY

(Submitted As Required per 21 CFR 807.92)

Substantial Equivalence:

Characteristic	Bovie Ultimate™ High Frequency Electrosurgical Generator (BVX-100H) (This Submission)	Bovie IDS-310 High Frequency Electrosurgical Generator (K134054) Primary Predicate	Bovie ICON GS Generator (GS100) (K090586) Secondary Predicate
Cut Modes	Has Two Cut Modes	Has Two Cut Modes	Not Applicable to this Device
Blend Modes	Has Three Blend Modes	Has Four Blend Modes	Not Applicable to this Device
Monopolar Connectors	One	Dual	Not Applicable to this Device
Plasma Connector	One	Not Applicable to this Device	One
Auto Bipolar	Does Not Have Auto Bipolar	Has Auto Bipolar	Not Applicable to this Device
Bovie Bipolar	Does Not Have Bovie Bipolar	Has Bovie Bipolar	Not Applicable to this Device
Output Gas Flow	1.0 – 5.0 Liters/minute	Not Applicable to this Device	1.0 – 5.0 Liters/minute
Bipolar Handpiece Activation	Supported	Supported	Not Applicable to this Device
Gas In Use Indicator	Present	Not Applicable to this Device	Not Present

Conclusions

The Bovie Ultimate™ High Frequency Electrosurgical Generator has the same intended use, operating procedures, principles of operation, and utilizes the same technology as the predicate devices. The Bovie Ultimate™ High Frequency Electrosurgical Generator does not raise additional issues of safety or efficacy compared to the predicate devices.